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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
09890001aa

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Application Number	Filed
09/921,595	August 6, 2001

First Named Inventor	
Slage	

Art Unit	Examiner
2157	Salad

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 32635

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

_____
Signature

Michael E. Whitham
Typed or printed name

703-787-9400
Telephone number

May 31, 2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Tradeamrk Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of

Slage — Confirmation No. 9500

Serial No. 09/921,595 — Group Art Unit: No. 2157

Filed August 6, 2001 — Examiner Salad

For SYSTEM AND METHOD FOR MANAGING, MANIPULATING, AND ANALYZING DATA AND DEVICES OVER A DISTRIBUTED NETWORK

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

ATTACHMENT TO PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

This Pre-Appeal Brief Request for Review is being concurrently filed with a Notice of Appeal. The Commissioner is authorized to charge attorney's deposit account 50-2041 (Whitham, Curtis, Christofferson & Cook) for any fee which would be required to for the notice of appeal and to gain entry and consideration of this pre-appeal brief request for review.

The Invention

The claimed invention is related to the conduct of clinical trials, and particularly to a system and method whereby prospective participants can identify clinical trials in which to participate, participants can execute steps by which they will be accepted or denied entry into a trial, and, after acceptance, participants are provided with a computerized module, and are permitted to provide data observations necessary for the clinical trial and these data observations can be used in the clinical trial.

This selection, acceptance, and participation aspect of the claimed methods and systems are highlighted below with reference to independent claims 2, 14, and 26.

Claim 2. A clinical trial data management server method, comprising:

receiving, at a server, a user profile provided by a client;

based on said user profile, indicating to said client one or more matching clinical trials;

receiving a clinical trail selection from said client;

providing to said client a selected clinical trial module, indicated by said clinical trial selection and corresponding to a selected one of said matching clinical trials, said module being adapted to obtain clinical trial data including a respective data observation;

receiving, at said server, said respective data observation;

storing said respective data observation in a database of data observations; and

in response to a report request:

retrieving selected ones of said data observations from said database in accordance with parameters in said report request to provide a plurality of observations; and

producing a report based on said plurality of retrieved observations.

Claim 14. A clinical trail data server, comprising:

a data engine receiving a user profile provided by a client;

clinical trials management module for analyzing said user profile and indicating to said client one or more matching clinical trials;

one or more clinical trial modules adapted to obtain clinical trial data, including respective data observations;

said clinical trials management module providing to said client a selected one of said one or more clinical trial modules, indicated by a clinical trial selection, and corresponding to a selected one of said matching clinical trials.

Claim 26. A clinical trial client for use on a computer, comprising:

a module for sending user profile to a clinical trial data server;

a module for receiving from said clinical trial data server an indication of one or more matching clinical trials;

a module for accepting a user selection of one of said one or matching clinical trials, and sending to said clinical trial data server a clinical trial solution; and

a module for receiving and installing a selected clinical trial module corresponding to said clinical trial selection, the selected clinical trial module

being adapted to obtain clinical trial data, including a respective data observation, from a clinical trial subject.

With reference to Figure 2 of the application, it can be seen that clinical trial recruitment 215 and data obtained from medical devices 310 and 330 which provide data which is used in the trial different aspects of the claimed invention. By contrasting Figures 4 and 5 of the application, it can be clearly seen that separate operations are performed for recruitment and participation in the trial.

Clinical trials can be lengthy processes involving many subjects and many many observations. The inventors have devised a method which allows people to be recruited, selected, and to begin participation in a secure and expeditious manner. Prior to the invention by the applicants, having rolling participation in clinical trials was more difficult and labor intensive. The invention allows people to be recruited and to start providing data useful for the trial on a rolling basis where entry of the participant, and receipt and handling of the data is performed by a computerized system which is secure and involves significantly less management effort than prior methods.

Errors and Omissions

The Examiner is in error in his finding that U.S. Patent Publication 2001/0051882 to Murphy anticipates each of claims 2 and 4-27. In fact, Murphy at most provides a matching system to match prospective participants to clinical trials. This is why the words "Match System" appear in box 110 on the face page of the patent.

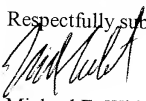
The Examiner erroneous concludes that "module 320 details of which is shown in fig. 5, is module sent from the server to the client to gather clinical trial information from the user" (page 2 of April 17, 2007 office action). As explained in paragraph [0024] of Murphy "The initial assessment 320 is comprised of a short questionnaire that is intended to gather information that will immediately narrow the list of trials for which the user may be a potential candidate" (emphasis mine). In short, NO DATA FOR A TRIAL is being provided by module 320. Module 320 simply is NOT adapted to obtain clinical trial data including a respective data observation as required in claims 2, 14 and 26.

With reference to Figure 5 of Murphy, which was referenced by the Examiner, it is noted that the first words on the screen are **Initial Assessment Questionaire**. With reference to paragraph [0024] it is clear that Murphy has a system for matching prospective participants to clinical trials in which they may participate, but Murphy does not show or contemplate an integrated system whereby prospective participants can review trials in which they might participate (through matching of information in a way which could be similar to or different from that shown in Murphy), apply to participate (and be rejected or accepted), and, if accepted, be provided with a module which is adapted to obtain clinical trial data. Note that in the practice of the invention, not everybody that has an interest in a clinical trial would get the clinical trial module. Some of them would not fit the criteria needed for the trial, a clinical trial might be closed after it receives all the desired participants, etc. The invention allows selection of participants, provisioning a module to participants for obtaining data, receiving data from participants, and being able to generate clinical trial reports and analysis based on the data. Murphy wholly lacks this integrated system concept and merely provides a matching process and system.

Conclusion

In view of the above, it is requested that the position of the Examiner be reviewed, that the rejection be withdrawn as the requirements of 35 U.S.C. 102(e) are clearly note met, and that the application be passed to issue.

Respectfully submitted,



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